UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,558	03/16/2000	Rolf W. Pfirrmann	1194-153	2302

6449 7590 02/25/2003

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
MAIER, LEIGH C	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 02/25/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/527,558	Pfirrmann
Examiner	**Art Unit**
Leigh Maier	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 27, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-4, 13, and 21-34* is/are pending in the application.

4a) Of the above, claim(s) *21-23* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4, 13, and 24-34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

Claims 5-12, 14, and 15 have been canceled. Claims 1-4 and 13 have been amended. Claims 24-34 have been added. Claims 1-4, 13, and 21-34 are pending. Claims 21-23 were previously withdrawn from consideration. Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 103

Claims 1-4 and 13 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over LEHNER (WO 98/28027) in view of REINMULLER (US 5,077,281). The references teach as set forth in the previous Office action.

Claim 1 has been amended to be limited to what was termed "Method A" in the previous Office action. This method is drawn the prevention of thrombosis formation on a liquid-containing surface of a liquid-delivery system comprising a regimen of forming a seal in the system containing taurolidine, taurultam, or a mixture thereof and an anticoagulant agent, other than taurolidine or taurultam.

Applicant's arguments filed November 27, 2002 have been fully considered but they are not persuasive.

Applicant first argues that each reference does not teach every limitation of the invention. In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references which is the case in the outstanding rejection. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant further argues that there is no motivation in the prior art for the proposed combination, as LEHNER is concerned with sepsis, while REINMULLER and the instant invention are concerned with the prevention of thrombosis. As discussed in the previous Office action, LEHNER teaches that taurolidine can reduce the adhesiveness of fibrin deposits which lead to thrombosis. Furthermore, REINMULLER also recognizes the dual functionality (bacteriocidal and coagulation-inhibiting action) of the taurolin derivatives in the reference. The examiner maintains that one of ordinary skill, having the teaching of LEHNER and REINMULLER, would recognize that sealing a taurolin derivative alone in the liquid-delivery system would be reasonably expected to prevent thrombosis. The addition of another anticoagulant would be obvious for the additive effect.

Claims 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over LEHNER (WO 98/28027) in view of RAAD et al (US 5,688,516). The references teach as set forth in the previous Office action.

The new claims are drawn to a method of preventing thrombosis formation on a liquid-containing surface of a liquid-delivery system comprising a regimen of: (1) first contacting surface with solution containing an anticoagulant agent other than taurolidine or taurultam; (2) thereafter contacting said surface with a solution containing taurolidine, taurultam, or a mixture thereof; and (3) repeating the contacting steps between delivery of liquids.

Applicant's arguments filed November 27, 2002 have been fully considered but they are not persuasive.

Applicant states that the references cannot be combined to suggest the instant invention. However, the references are clearly drawn to same field of endeavor and are suitable for combining in order to make the instant invention obvious.

The examiner maintains that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of treating a liquid delivery system as taught by LEHNER by first flusing the liquid-delivery system with an anticoagulant, as is the standard of care taught by RAAD. One of ordinary skill would reasonably expect success in thrombosis prevention in addition to the prevention of infection, as taught by LEHNER, by implementing this two-step process. It would be within the scope of the artisan to select any appropriate anticoagulant for this purpose. It would be obvious to repeat these flushing steps after liquid delivery in order to clear away any remaining delivered material, maintain patency and prevent infection. It would be further obvious to seal the taurolidine in the liquid-delivery system between uses, as taught by LEHNER.

Claims 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over LEHNER (WO 98/28027) and RAAD et al (US 5,688,516) and further in view of ITO et al (US 5,167,960). The references teach as set forth in the previous Office action.

The invention is as set forth above. Claim 33 recites a number of anticoagulant species.

Applicant's arguments filed November 27, 2002 have been fully considered but they are not persuasive.

Applicant states that LEHNER and RAAD cannot be combined to suggest the instant invention, and ITO fails to remedy the alleged deficiencies. Again, the examiner does not find any reasoning to support this statement.

LEHNER and RAAD teach as set forth in the previous Office action. These references do not teach the full range of anticoagulants recited in claim 33. However, as set forth above, RAAD does expressly suggest the use of other anticoagulants.

ITO teaches the use of other thrombogenesis inhibitors, such as hirudin and ticlopidine, in liquid delivery systems. See abstract and col 1, lines 44-50.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the LEHNER process by first flusing the liquid-delivery system with an anticoagulant, as is the standard of care taught by RAAD, as discussed above. It would have been within the scope of the artisan to select any known thrombogenesis inhibitor for this purpose. It would be in the scope of the artisan to optimize the amount of thrombogenesis inhibitor with routine experimentation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, or Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
February 21, 2003

KATHLEEN K. PONDA
PRIMARY EXAMINER